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The National Bio- and Agro-Defense Facility: Issues for Congress

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The National Bio- and Agro-Defense Facility: Issues for Congress

Summary

The agricultural and food infrastructure of the United States is potentially susceptible to terrorist attack using biological pathogens. In addition to the impacts of such an attack on the economy, some animal diseases could potentially be transmitted to humans. These diseases are known as zoonotic diseases. Scientific and medical research on plant and animal diseases may lead to the discovery and development of new diagnostics and countermeasures, reducing the risk and impact of a successful terrorist attack.

To safeguard the United States against animal disease, Congress has appropriated funds to the U.S. Department of Agriculture (USDA) to engage in research at the Plum Island Animal Disease Center (PIADC), off the coast of New York, on animal diseases not native to the United States. When creating the Department of Homeland Security (DHS) in 2003, Congress transferred the PIADC facility from USDA to DHS. Both USDA and DHS, in cooperation with USDA, conduct foreign animal disease research at PIADC, but PIADC has been identified as outdated and too limited to continue as the primary facility for this research.

Homeland Security Presidential Directive 9 tasks the Secretaries of Agriculture and Homeland Security to develop a plan to provide safe, secure, and state-of-the-art agriculture biocontainment laboratories for research and development of diagnostic capabilities and medical countermeasures for foreign animal and zoonotic diseases. To partially meet these obligations, DHS has requested Congress to appropriate funds to construct a new facility, the National Bio- and Agro-Defense Facility (NBAF). This facility would house high-containment laboratories able to handle the pathogens currently under investigation at PIADC, as well as other pathogens of interest. Six candidate sites have been identified, one of which is Plum Island. The DHS plans to select the site in 2008 and open NBAF in 2014. The final construction cost will depend on the site location and may exceed the $451 million projected total cost. Additional expenses, such as equipping the new facility, relocating existing personnel and programs, and preparing the PIADC facility for disposition, may reach an additional $100 million. The DHS has not yet determined what actions to take with the PIADC when construction of the NBAF is completed.

The plans announced by DHS to establish the NBAF have raised several issues. Community concerns about safety and security, previously raised about PIADC and other laboratories being built to study dangerous pathogens, are also being raised about the NBAF. Coordination between DHS and USDA, as well as prioritization and investment in agricultural biodefense, may be reassessed once more high-containment laboratory space becomes available.

By law, research on live foot and mouth disease (FMD) virus is not permitted on the U.S. mainland. This policy would need to be changed before DHS could conduct FMD research at NBAF if it were sited on the U.S. mainland. The conference agreement to the 2008 farm bill, H.R. 2419, as well as H.R. 1717, address possession of live FMD virus by DHS.

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Introduction

The agricultural and food infrastructure of the United States is a key component of economic productivity and growth. A terrorist attack on this infrastructure could damage the public trust in agricultural safety and quality and the nation's ability to provide food and other agricultural products.[1] Additionally, many animal diseases can infect humans.[2] These types of diseases are termed *zoonotic*. Scientific and medical understanding of such zoonotic diseases in their animal hosts may protect the animals themselves and could also lead to the discovery and development of new medical countermeasures for humans.

To safeguard the United States against the impacts of naturally occurring and intentional animal disease outbreaks, the U.S. Department of Agriculture (USDA) engages in animal disease research, including research into highly contagious animal pathogens and animal diseases not native to the United States.[3] Such research activities have historically been performed at the Plum Island Animal Disease Center (PIADC), located on an island near Long Island, NY.

When creating the Department of Homeland Security (DHS) in 2003, Congress transferred the operation of the PIADC facility from USDA to DHS, though USDA still maintains an active research program at PIADC. The DHS, in cooperation with USDA, has established its own research and development program at PIADC. As the federal government undertakes new efforts in human biodefense and defense against agroterrorism, DHS has identified the PIADC facility as "reaching the end of its life cycle" and lacking critical capabilities to continue as the primary facility performing this research.[4]

Homeland Security Presidential Directive 9 (HSPD-9) tasks the Secretaries of Agriculture and Homeland Security to develop "a plan to provide safe, secure, and state-of-the-art agriculture biocontainment laboratories that research and develop

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[1] For more background on the potential of terrorism against agriculture and food, see CRS Report RL32521, *Agroterrorism: Threats and Preparedness*, by Jim Monke.

[2] Examples include influenza, plague, West Nile Virus, and Rift Valley Fever.

[3] These diseases are sometimes referred to as foreign animal diseases (FAD).

[4] Department of Homeland Security, FY2006 Science and Technology Directorate congressional budget justification, p. 44.

diagnostic capabilities for foreign animal and zoonotic diseases."[5] The Secretary of Homeland Security is to coordinate an acceleration and expansion of the development of current and new countermeasures against the intentional introduction or natural occurrence of catastrophic animal, plant, and zoonotic diseases, including

> countermeasure research and development of new methods for detection, prevention technologies, agent characterization, and dose response relationships for high-consequence agents in the food and the water supply.[6]

The Department of Homeland Security has announced that, to meet the obligations of HSPD-9, it will establish a new facility, the National Bio- and Agro-Defense Facility (NBAF).[7] This facility would have high-containment laboratories able to hold the pathogens currently under investigation at PIADC as well as other pathogens of interest. The plans announced by DHS to establish the NBAF have raised congressional and public concerns regarding its safety and security and policy questions about coordination between DHS and USDA regarding the research to be conducted at NBAF.

The DHS has narrowed the number of possible sites for the NBAF to six. The sites are located in Athens, GA; Manhattan, KS; Madison County, MS; Granville County, NC; San Antonio, TX; and Plum Island, NY.[8] Each site is currently preparing an Environmental Impact Statement for the location.

This report outlines current progress towards establishment of the NBAF, presents current and projected funding levels and timelines, and describes policy issues of potential interest to Congress, such as agency coordination, possession of viruses, construction timelines, disposition of PIADC, and community safety concerns.

NBAF Research Goals

The DHS intends the new NBAF to be more than just a replacement facility for PIADC; DHS intends it to exceed both the capacity and capabilities of the existing Plum Island laboratories. The highest level of biocontainment available at PIADC is Biosafety Level 3 Agricultural (BSL-3Ag).[9] Because DHS plans to perform

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[5] Executive Office of the President, The White House, "Subject: Defense of United States Agriculture and Food," *Homeland Security Presidential Directive/HSPD-9*, January 30, 2004.

[6] Ibid.

[7] 72 *Fed. Reg.* 41764-41765 (July 31, 2007).

[8] 72 *Fed. Reg.* 41764-41765 (July 31, 2007).

[9] Biosafety levels for pathogens and the recommended protective measures at each biosafety level are developed by the Department of Health and Human Services. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*, 5th Edition, (continued...)

experiments with some pathogens that require a higher level of protection, approximately 10% of the NBAF's net square footage would be BSL-4 laboratories.[10]

The DHS foresees multiple uses and goals for the new facility:

- serving as a unique BSL-3 and BSL-4 livestock laboratory capable of developing countermeasures for foreign animal diseases;
- providing advanced test and evaluation capability for threat detection, vulnerability assessment, and countermeasure assessment for animal and zoonotic diseases; and
- supporting countermeasure licensure.[11]

The research agenda for NBAF is to be at least partially based on current risk assessments and subject to change as the risk assessments change. The DHS predicts that the facility will focus on foot and mouth disease (FMD), classical swine fever, African swine fever, Rift Valley fever, Nipah virus, Hendra virus, contagious bovine pleuropneumonia, and Japanese encephalitis.[12] The DHS plans to perform research at NBAF to study how these pathogens enter the animal, what types of cell the disease affects, what effects the disease has on cells and animals, and how newly developed countermeasures help the animal develop protection against the disease.

NBAF Funding and Site Selection

Funding

In the DHS Science and Technology FY2006 congressional budget justification, DHS provided a NBAF project schedule that included a summary of major milestones, a projected time line for meeting the milestones, and projected funding

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[9] (...continued)
February 2007, available online at [http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm]. The BSL-3Ag containment level was established by the USDA for research with certain pathogens in large animal species. U.S. Department of Agriculture, Agricultural Research Service, *ARS Facilities Design Standards*, 242.1-M ARS, July 24, 2002, available online at [http://www.afm.ars.usda.gov/ppweb/PDF/242-01M.pdf].

[10] For example, research on Nipah virus must be performed in a BSL-4 laboratory. Since the United States has limited space to perform large animal research under BSL-4 containment, U.S. scientists have gone outside the country, for example to Canada, to conduct such experiments. Testimony by James Roth, Director, Center for Food Security and Public Health, Iowa State University, before the Senate Committee on Agriculture, Nutrition, and Forestry, on July 20, 2005, available online at [http://agriculture.senate.gov/Hearings/hearings.cfm?hearingid=1572&witnessId=4472].

[11] 71 *Fed. Reg.* 3107-3109 (January 19, 2006).

[12] Department of Homeland Security, *Facility Research & Staffing for the National Bio and Agro-Defense Facility*, June 12, 2007. Available online at [http://www.dhs.gov/xres/labs/gc_1181073261627.shtm].

requirements by fiscal year to launch operation of a new facility in 2010. See **Table 1**.

Table 1. Initially Projected NBAF Construction Funding Requirements (2005)

($ in millions)

FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	Total
3	23	73	129	129	94	451

Source: DHS Science and Technology Directorate, FY2006 congressional budget justification.

Actual NBAF funding has not followed this schedule. See **Table 2**. The DHS has requested, and received, appropriations at a lower level than initially projected in 2005. The DHS Science and Technology FY2006 congressional budget justification stated that NBAF funding began in FY2005 when "$3 M was received for a planning and feasibility study from base funding of Biological Countermeasures."[13] However, DHS has subsequently clarified that the FY2005 funding was used elsewhere in DHS and that FY2006 and FY2007 appropriations funded these studies.[14] In FY2006, Congress appropriated $23 million to select a site and conduct other pre-construction activities.[15] In FY2007, an additional $23 million was appropriated for site selection and other pre-construction activities.[16] The FY2007 DHS Appropriation Act also included a $125 million rescission of unobligated prior year appropriations from Science and Technology Directorate accounts. As part of its implementation of this law, DHS removed $11 million from the FY2006 NBAF appropriation.[17] In FY2008, Congress appropriated $11 million to continue environmental studies necessary to select a site for the NBAF.[18] For FY2009, the President's budget requests $35.6 million to continue progress on the NBAF construction.

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[13] Department of Homeland Security, FY2006 Science and Technology Directorate congressional budget justification, p. 45.

[14] Department of Homeland Security, personal communication, September 10, 2007.

[15] H.Rept. 109-241 to accompany H.R. 2360 (P.L. 109-90), p. 78.

[16] H.Rept. 109-699 to accompany H.R. 5441 (P.L. 109-295), p. 168.

[17] Department of Homeland Security, personal communication, September 10, 2007.

[18] P.L. 110-161, Consolidated Appropriations Act, 2008.

Table 2. NBAF Construction Funding

($ in millions)

Action	FY2005	FY2006	FY2007	FY2008	FY2009
DHS Allocation	3				
DHS Reallocation	(3)				
P.L. 109-90		23			
P.L. 109-295		(11)	23		
P.L. 110-161				11	
FY2009 Budget Request					36
Total Appropriations	**0**	**12**	**23**	**11**	
Annual Costs Projected in 2005 (from **Table 1**)	3	23	73	129	129

Source: Funding rounded to nearest million. CRS calculations based on DHS congressional budget justification, H.Rept. 109-241, H.Rept. 109-699, and DHS personal communication.

The DHS has changed the expected completion date for the NBAF facility from 2010 to 2014.[19] An updated full cost schedule is not publicly available. In the February 2005 projection, DHS anticipated requesting funding throughout the construction process, including 2010, the year DHS expected to open the facility. This raises questions about whether the total cost of the NBAF facility will increase due to the extension of the construction schedule. Subsequent DHS budget requests have not updated the projected overall funding requirements. It remains unclear how this delay will affect the future annual appropriations requests and the total cost of the project.[20]

The DHS *Science and Technology Five-Year Research Plan* projects the NBAF costs to be $436.5 million for FY2007-FY2011. Including the $12 million in FY2006 brings the cumulative total for FY2005-FY2011 to $448.5 million. See **Table 3**. The DHS states that the overall construction cost will depend on the site selected and that site-specific infrastructure costs may increase the total cost above

[19] Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2007-2011*, May 2007.

[20] The DHS was directed to "submit a project schedule, including expected completion dates and funding requirements for all phases of the project, to the Committees on Appropriations." See H.Rept. 109-699 to accompany P.L. 109-295, p. 168.

$451 million.[21] Additional delays to the construction schedule may further change the final cost of the facility due to changing material and labor costs.[22]

Table 3. Changing NBAF Funding Projections

($ in millions)

Year of Projection	FY05	FY06	FY07	FY08	FY09	FY10	FY11	Total
2005	3.0	23.0	73.0	129.0	129.0	94.0	0	451.0
2007	0[a]	12.0[a]	23.0	11.0	45.6	184.9	172.0	448.5[b]

Source: CRS calculations and DHS FY2006 congressional budget justification; Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2007-2011*, May 2007; and DHS, personal communication September 10, 2007.

a. These numbers were not included in the DHS projection, but are taken from actual funding, see **Table 2**.

b. The DHS did not include costs beyond FY2011 in this five year projection, although they predict construction to continue until 2014.

The two DHS project schedules differ in the pace of anticipated funding requests. The initial NBAF project schedule planned to receive the bulk of its appropriated construction funding in the years immediately before facility completion. In contrast, the funding schedule provided in the *Five-Year Research and Development Plan, Fiscal Years 2007-2011* plans to receive the bulk of the NBAF construction funding up to four years prior to facility completion. The DHS may be attempting to account for NBAF's full funding requirements within the 2007 five-year plan.[23]

Not included in the projected construction costs are equipment and relocation expenses involved in transferring the research projects of PIADC to the NBAF.[24] These costs are variable, as they depend on the final location of the NBAF, the

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[21] Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2007-2011*, May 2007 and Department of Homeland Security, personal communication, September 10, 2007.

[22] Material and labor costs may be higher or lower at the time of construction than at the time of the initial projection. An increase in total cost due to increased material expense occurred during construction of another DHS high containment biological laboratory, the National Biodefense Analysis and Countermeasures Center. See CRS Report RL32891, *The National Biodefense Analysis and Countermeasures Center: Issues for Congress*, by Dana A. Shea.

[23] The DHS states that no additional funds beyond those reported in the five year plan are expected to be requested, barring site-specific infrastructure costs. DHS, personal communication, September 10, 2007, and DHS, personal communication, October 4, 2007.

[24] Similar move-in costs will be incurred following the completion of the NBACC facility. Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification*.

number of research projects to be transferred, and the particular equipment needs identified. They have been reportedly estimated by DHS as up to $100 million.[25]

Facility Site Selection

The DHS has stated that the establishment of the NBAF would be a multi-stage process. This process involves:

- obtaining expressions of interest to be the site of the NBAF;
- selecting prospective sites from these expressions of interest and requesting further information;
- assessing the information provided and visiting these prospective sites;
- narrowing the number of prospective sites to a list of final sites;
- preparing environmental impact studies of the final sites;
- choosing a site for the NBAF; and
- constructing the facility.

The stages of the DHS process will be addressed below. The DHS is now at the stage of requiring environmental impact studies of the final potential sites. The final potential sites are listed below in **Table 5**. The DHS has stated it plans to choose the final site by October 2008.[26]

Expressions of Interest. In January 2006, DHS issued a Request for Expressions of Interest from consortia interested in hosting NBAF. Consortia responding to the DHS request included academia, industry, and non-profit institutes. In its request, DHS described four criteria that the agency would use when considering the expressions of interest:

- research capabilities,
- workforce,
- acquisition/construction/operating expertise, and
- community acceptance.[27]

Prospective Sites. In August 2006, DHS selected, from the 29 expressions of interest, 18 sites to submit more information with respect to the four criteria. One site was later removed from consideration by its sponsoring consortium. Although 17 sites were under consideration, only 12 consortia were involved, as some

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[25] As cited in *Letter from Marc L. Kesselman, U.S. Department of Agriculture, to Representatives John D. Dingell and Bart Stupak*, December 18, 2007.

[26] Testimony by John Vitko, Jr., Head, Chemical and Biological Division, Science and Technology Directorate, Department of Homeland Security, before the House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, on May 23, 2007.

[27] 71 *Fed. Reg*. 3107-3109 (January 19, 2006).

consortia submitted multiple possible sites that were selected by DHS.[28] See **Table 4**. An intergovernmental review group, which included DHS, USDA, the Department of Health and Human Services, and the Department of Defense, assessed the additional information. The DHS then visited each site to validate the information provided and to observe the sites.

Table 4. Consortia Selected by DHS after Expression of Interest

Consortium	Site Location
University of California/Lawrence Livermore National Laboratory	CA
Georgia Consortium for Health and Agro-Security (2 sites)	GA
Heartland BioAgro Consortium (2 sites)	KS
Kentucky and Tennessee NBAF Consortium	KY
Mid-Atlantic Bio-Ag Defense Consortium	MD
Gulf States Bio and Agro-Defense Consortium (3 sites)[a]	MS
University of Missouri at Columbia NBAF Consortium	MO
North Carolina Consortium for the NBAF	NC
Oklahoma State University Consortium	OK
Texas A&M University and the NBAF Consortium	TX
Texas Biological and Agro-Defense Consortium (3 sites)	TX
Wisconsin Consortium	WI

Source: DHS, online at [http://www.dhs.gov/xres/labs/gc_1170798884583.shtm].
a. One site was withdrawn from consideration in April 2007.

Finalists. Following the site visits, DHS selected five sites in July 2007 to complete an Environmental Impact Statement (EIS). Also, DHS included Plum Island as a candidate site. See **Table 5**. The DHS has requested public input into the selection process through the EIS process and public hearings.[29] Following completion of the EISs, DHS expects to choose a site by October 2008.

[28] See online at [http://www.dhs.gov/xres/labs/gc_1170798884583.shtm].

[29] Additional information on the potential sites and dates for public meetings about the EIS are available at 72 *Fed. Reg.* 41764-41765 (July 31, 2007).

Table 5. Finalists for NBAF Site

Consortium	Location
Georgia Consortium for Health and Agro-Security	University of Georgia Athens, GA
Heartland BioAgro Consortium	Kansas State University Manhattan, KS
Gulf States Bio and Agro-Defense Consortium	Flora Industrial Park Madison County, MS
North Carolina Consortium for the NBAF	Umstead Research Farm Granville County, NC
Texas Biological and Agro-Defense Consortium	Texas Research Park San Antonio, TX
Department of Homeland Security[a]	Plum Island, NY

Source: DHS, online at [http://www.dhs.gov/xres/labs/gc_1184180641312.shtm] and 72 *Fed. Reg.* 41764-41765 (July 31, 2007).

a. According to DHS, although not included in the competitive selection process described above, the DHS-owned PIADC will also be considered as a potential NBAF site.

Policy Issues

Policy issues relating to NBAF include limits on possession of certain pathogens, the need for and scope of NBAF, coordination among agencies, the NBAF construction schedule, disposition of PIADC or Plum Island, and community concerns. Congress has passed the conference agreement on the 2008 farm bill, H.R. 2419, and also considered H.R. 1717 as reported by the House Homeland Security Committee, both of which would affect NBAF operations. The Administration, through USDA, also has proposed legislative language to authorize the establishment of NBAF and, through DHS, to provide authority for the sale of Plum Island.

Level of Protection Against Pathogen Release

A release of pathogens is a potential risk of high-biocontainment laboratories, but the likelihood that a pathogen would be accidentally released from the laboratory into the surrounding area is generally considered to be low. To protect against such accidental release, the Department of Health and Human Services and the USDA have developed guidelines for the construction, maintenance, and operation of high-biocontainment laboratories. These guidelines take into account the properties of the pathogen and the types of experiments being performed. The established biocontainment levels have increasing levels of rigor, and these biocontainment protocols are adhered to as a matter of best practice in government, academic, and industrial laboratories.[30]

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[30] Centers for Disease Control and Prevention and National Institutes of Health, Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories,* (continued...)

In addition to the safety precautions established by these biocontainment guidelines, some pathogens have been deemed to require additional layers of protection.[31] One pathogen so considered is foot and mouth disease (FMD). As it is considered highly contagious and to have the potential to seriously harm the national economy if domestic livestock or other animals are infected, importation of FMD virus is prohibited, and research on live FMD virus currently is limited to locations outside of the mainland of the United States. The conduct of FMD virus research on an island was perceived as providing a geographic barrier to infection of domestic livestock in the case of an accidental release. Only if the Secretary of Agriculture provides an explicit permit under 21 U.S.C. 113a may research on live FMD virus be performed on the mainland of the United States.[32] Currently, the USDA performs FMD research only at PIADC.

Security concerns regarding the potential for terrorist use of pathogens also has led to the application of registration of researchers and facilities that work with or possess certain "select agents." The PIADC must conform to the regulations of the Agricultural Select Agent Program promulgated by USDA, and the NBAF would as well.[33] Under these regulations, biological agents, such as pathogens and toxins, that pose a severe threat to public, animal, or plant health have been identified and listed as "select agents." The FMD virus is a select agent. Entities that possess, use, or transfer these select agents are required to develop security plans for protecting the select agents, register with the USDA Animal and Plant Health Inspection Service (APHIS), and become certified as eligible to possess select agents. Researchers handling select agents must pass a security review by the Department of Justice.

Even with these guidelines and regulations in place, some activists have been concerned that these protections may be insufficient. Operation of PIADC has engendered some controversy among nongovernmental organizations and others, who have expressed concerns about the potential for pathogen release, illicit research, and unintended consequences.[34] Local opposition also increased following suggestions of upgrading the biocontainment facilities from BSL-3Ag to BSL-4 to

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[30] (...continued)
5th Edition, February 2007, online at [http://www.cdc.gov/OD/ohs/biosfty/bmbl5/BMBL_5th_Edition.pdf].

[31] An example is smallpox virus, which is only allowed to be possessed by one U.S. laboratory, the Centers of Disease Control and Prevention in Atlanta, GA.

[32] Because of concerns about the economic damage that might arise from the release of the pathogen that causes foot and mouth disease into domestic animal stocks, Congress enacted prohibitions in 1948 against performing research within the mainland of the United States. 21 U.S.C. 113a prohibits the Secretary of Agriculture from introducing live foot and mouth disease virus to the mainland of the United States unless the Secretary determines it is necessary and in the public interest.

[33] The agricultural select agent regulations are codified at 9 C.F.R. 121 and 7 C.F.R. 331. A comparable program exists for select agents that might infect humans. It is overseen by the Centers for Disease Control and Prevention on behalf of the Department of Health and Human Services. These select agent regulations are codified at 42 C.F.R. 73.

[34] John Rather, " Heaping More Dirt On Plum I.," *New York Times,* February 15, 2004, and Beth Daley, "Danger Island," *Boston Globe,* September 11, 2001.

allow work on more dangerous pathogens. Those suggestions were not acted upon.[35] Questions regarding worker safety and the potential for human infections by pathogens that affect both humans and animals have also been raised.[36] The DHS, through informational sessions in the EIS process, has attempted to allay these concerns and has stated that community acceptance, or at least minimal community resistance, is one of the NBAF site criteria. However, continued community outreach may be a key factor in determining whether NBAF will suffer delays that have threatened construction of other high-containment laboratories.[37]

The focus of some community concerns has been the potential for an FMD outbreak to occur following an accidental or deliberate release of FMD virus from the proposed NBAF. The likelihood of such a release is difficult to quantify. Accidental releases of FMD virus from research laboratories have occurred in the United Kingdom.[38] Historically, FMD virus was accidentally released from PIADC in 1978, though no infected animals reached the mainland and the foot and mouth disease outbreak was contained to Plum Island.[39] More recently, in 2004, FMD virus was discovered outside of research laboratories but still within PIADC.[40] Should the NBAF be sited on the mainland, such an outbreak might be more difficult to contain. Some argue that FMD virus research should not be performed on the mainland but instead remain offshore and retain a geographic barrier to help contain an outbreak.[41] Biocontainment technologies have advanced since the PIADC FMD virus release,

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[35] John Rather, "East End Germ Lab Getting an Upgrade," *New York Times*, November 25, 2001.

[36] Occupational exposure to dangerous, federally regulated pathogens in a laboratory at Boston University and Texas A&M University are cited as examples of such events. (M. Anita Barry, *Report of Pneumonic Tularemia in Three Boston University Researchers, November 2004 — March 2005*, Boston Public Health Commission, March 28, 2005 and Emily Ramshaw, "CDC Suspends A&M Research on Infectious Diseases; CDC Suspends Bioagent Work after Exposures Not Reported Promptly," *The Dallas Morning News*, July 2, 2007.)

[37] Barbara Goodson, "Judge Hits BU Biolab; Ruling Calls for Safety Review, May Stall Plan," *The Boston Herald*, August 4, 2006.

[38] The July/August 2007 FMD outbreak in the United Kingdom has been associated with a likely breach of biosecurity in a waste water drainage system at the nearby Pirbright research facility. The investigation also identified inadequate controls on the movement of people and vehicles from the site. (Health and Safety Executive, *Final Report on Potential Breaches of Biosecurity at the Pirbright Site 2007*, September 7, 2007, available online at [http://www.hse.gov.uk/news/archive/07aug/finalreport.pdf]. See also Martin Enserink, John Travis, and Jocelyn Kaiser, "Labs Suspected in Foot-and-Mouth Crisis," *ScienceNOW Daily News*, August 6, 2007.)

[39] Nicholas Wade, "Cattle Virus Escapes from a P4 Lab," *Science*, Vol. 202, October 20, 1978, p. 290, and Nicholas Wade, "Accident and Hostile Citizens Beset Animal Disease Laboratory," *Science*, Vol. 202, November 17, 1978, pp. 723-724.

[40] Bill Bleyer, "Clinton, Bishop Complain of 'Breach': Plum I. Lab Tightens Biosafety," *Newsday*, August 17, 2004, and John Rather, "Plum Island Reports Disease Outbreak," *New York Times*, August 22, 2004.

[41] Emily Ramshaw, "Texas May Be Home to New Foot-and-mouth Disease Research Lab," *Dallas Morning News*, November 11, 2007.

and DHS argues that modern biocontainment technology is sufficient to prevent an accidental release.[42]

The consequences of an environmental pathogen release would depend on the location of the laboratory. A release of an animal pathogen into an area without a natural host may have relatively low consequences. Alternatively, the release of a highly contagious pathogen into an area densely populated with potential hosts could have relatively high consequences. An accidental or deliberate release of FMD virus could lead to an FMD outbreak in domestic animals. The consequences of an FMD outbreak within the United States could be high.[43]

Permission to Work with Foot and Mouth Disease. When PIADC was transferred to DHS, the Secretary of Agriculture retained the authority to prevent FMD research from being performed on the mainland of the United States. If the NBAF is located on the mainland of the United States and is to perform high-value foreign animal disease research, researchers at the facility will likely need to receive such permission from the Secretary of Agriculture to perform FMD research.[44]

While some experts might construe this permission as a formality, since, under HSPD-9, DHS and USDA are to coordinate their activities in food and animal disease research, others might see it as a potential barrier to effective and efficient

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[42] See, for example, oral testimony of John Vitko, Head, Chemical and Biological Division, Science and Technology Directorate, DHS, before the House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, on May 23, 2007.

[43] Estimates of the economic impact of an FMD outbreak vary. A 2002 Purdue University and USDA study found that an FMD outbreak in the U.S. similar to the 2001 outbreak in the United Kingdom could reduce farm income by $14 billion. Price Waterhouse Coopers determined loss ratios for the 2001 U.K. outbreak. When applied to the U.S. livestock industry, the potential impact is estimated at $10 billion to $33 billion. A University of California study in 1999 estimated the potential impacts of an FMD outbreak in California at between $8.5 and $13.5 billion. (Beth Lautner and Steve R. Meyer, "U.S. Agriculture in Context: Sector's Importance to the American Economy and Its Role in Global Trade," in Terrence K. Kelly, Peter Chalk, James Bonomo, John Parachini, Brian A. Jackson, and Gary Cecchine, *The Office of Science and Technology Policy Blue Ribbon Panel on the Threat of Biological Terrorism Directed Against Livestock*, CF-193-OSTP, 2004, pp. 111, 113-114, available online at [http://www.rand.org/pubs/conf_proceedings/2005/CF193.pdf]). A 2002 National Defense University study estimated that a limited outbreak of FMD on just 10 farms could have a $2 billion financial impact. (Henry S. Parker, *Agricultural Bioterrorism: A Federal Strategy to Meet the Threat*, McNair Paper 65, National Defense University, March 2002, available online at [http://www.ndu.edu/inss/McNair/mcnair65/McN_65.pdf]).

[44] The Administrator of the Agricultural Research Service, Department of Agriculture, has testified, "It is our expectation that the Secretary of Agriculture will authorize FMD work to be done on the mainland in NBAF, and that would be for all agencies. The USDA programs now at Plum Island will be a component of the NBAF facility. So yes, the Secretary of Agriculture intends to do that." See Testimony by Edward Knipling, Administrator, Agricultural Research Service, Department of Agriculture, before the House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, on May 23, 2007.

use of the NBAF. They might seek to provide the Secretary of DHS with independent authority to perform FMD research.

2008 Farm Bill, H.R. 2419. On May 14, 2008, the House passed the conference agreement on the 2008 farm bill, H.R. 2419, by a vote of 318-106. On May 15, 2008, the Senate passed the same bill by a vote of 81-15. Section 7524 of the conference agreement would require USDA to issue a permit to DHS for live FMD virus research at the successor facility to the PIADC. The provision states that, once issued, the permit can only be suspended, revoked, or otherwise impaired if the Secretary of Agriculture determines that the FMD research is not being carried out in compliance with the select agent regulations.

The White House has promised to veto H.R. 2419 because of the size of funding for programs in the bill generally and a perceived lack of reform in farm subsidy programs. Given that the floor votes on the conference agreement exceeded a two-thirds majority in both chambers, a veto override may be possible.[45]

USDA's Proposal. The USDA's comprehensive proposal for the farm bill included a provision to revise 21 U.S.C. 113a.[46] The USDA provision would allow USDA to conduct research on foot and mouth disease on the U.S. mainland. It would prohibit anyone else from importing, transporting, or maintaining viruses that would be on a USDA-prescribed list, unless the Secretary of Agriculture issues a permit. However, the USDA provision also states it would not apply to select agents. This last section of USDA's proposal appears to negate the previous two provisions with respect to FMD virus, since FMD virus is an agricultural select agent.

The USDA proposal appears to be inherently contradictory, as it establishes a prohibition against entities other than the Secretary of Agriculture possessing FMD virus without the permission of the Secretary of Agriculture, but then exempts FMD virus from these prohibitions. The net effect of the USDA provision may be removal of any permitting restrictions for FMD virus, thus allowing research to be performed by those compliant with the agricultural select agent regulations.

The House-passed version of the farm bill in July 2007 contained most of the USDA proposal for foreign animal disease research laboratories (section 7108 of House-passed H.R. 2419), including the apparently contradictory language that exempts select agents from the permit requirements established in the bill.

H.R. 1717. As amended by the House Homeland Security Committee, H.R. 1717 would instruct USDA to issue a permit to DHS for FMD research at the NBAF. Other existing requirements under the agricultural select agent regulations would

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[45] For more information on the 2008 farm bill, see CRS Report RL33934, *Farm Bill Legislative Action in the 110th Congress*, by Renee Johnson, Geoffrey S. Becker, Tom Capehart, Ralph M. Chite, Tadlock Cowan, Ross W. Gorte, Charles E. Hanrahan, Remy Jurenas, Jim Monke, Jean M. Rawson, Randy Schnepf, Joe Richardson, Donald J. Marples, and Mark Jickling.

[46] See USDA's farm bill proposal, section 7303, online at [http://www.usda.gov/documents/fbresearch0507_1.pdf].

continue to apply, and DHS would have to meet them for the permit to remain valid. Although this provision would compel USDA to issue a permit allowing DHS to possess the virus, it would continue to vest authority for determining who may possess the virus with USDA. H.R. 1717, as introduced, would have given DHS independent authority to possess FMD virus, notwithstanding 21 U.S.C. 113a.[47]

Analysis. H.R. 1717, the conference agreement of the farm bill, and the Administration's proposal have different ramifications for DHS's possession of FMD and other high-consequence animal disease viruses. H.R. 1717 and the farm bill conference agreement would make DHS eligible to possess and conduct research with FMD and other high consequence animal viruses through a USDA permit under 21 U.S.C. 113a. This eligibility would be still subject to USDA's authority to revoke its mandated permit, as well as its authority under the agricultural select agent regulations.

Under the Administration's proposal, the language could have led to possibly contradictory interpretations. The apparent contradiction in establishing a permitting process for FMD virus possession — while excluding select agents, including FMD virus, from this permitting process — might have led to confusion in the interpretation of the regulatory effect of this language. This contradiction could be resolved if USDA chose to no longer regulate FMD virus as a select agent, a decision within its authority. However, this action might be viewed as weakening other important security controls on FMD virus. Additionally, the related House-passed version of the farm bill in July 2007 might be interpreted as revising 21 U.S.C. 113a or instead as retaining 21 U.S.C. 113a and establishing a parallel permitting process. Finally, a plain text reading might even lead to the interpretation that FMD virus research is not allowed, as this section authorizes the establishment of research laboratories working on "animal diseases in the United States," something that FMD arguably is not, rather than the establishment of research laboratories in the United States working on animal diseases.[48]

Need for and Scope of NBAF

Other agencies and organizations in addition to DHS have identified needs that could be met by the NBAF. At least as early as 1999, USDA recognized a need for a BSL-4 facility capable of handling large animals. In response to a mandate by Congress,[49] USDA commissioned a strategic planning task force that recommended that the "Agricultural Research Service must consider upgrading current Level 2 and Level 3 bio-containment units for animals and constructing a Level 4 unit."[50] In 2005, the National Research Council (NRC) echoed the need for a BSL-4 facility

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[47] See footnote 32.

[48] H.R. 2419, section 7108 (b) (2).

[49] P.L. 104-127, Subtitle D, section 884.

[50] USDA, "Report on the Strategic Planning Task Force on USDA Research Facilities: Report and Recommendations," August 1999, p. 24.

capable of handling large animals. The NRC also concluded that PIADC was at the end of its life cycle and that it should be "replaced urgently."[51]

While USDA and DHS have repeatedly stated their need for a new BSL-4 facility, it is less clear how large this facility should be. In response to questions for the hearing record, DHS asserted that

> Site criteria and requirements for NBAF were developed by an interagency technical working group, including DHS, USDA, and HHS to evaluate sites that would best support research in high-consequence animal and zoonotic diseases in support of Homeland Security Presidential Directives, HSPD-9 and HSPD-10.[52]

The DHS has not publically released supporting documentation relating to the working group's deliberations.

The DHS projects the size of the NBAF to be approximately 504,000 gross square feet.[53] Approximately 55,000 gross square feet of the facility would be BSL-4 laboratory space. See **Table 6**. This facility would be more than twice as large as the existing PIADC facility.[54] This sizeable increase in laboratory capacity may meet the requirements put forth by HSPD-9, as well as establishing the expanded, modern facilities to replace PIADC and perform necessary research activities. Full use of this expanded laboratory space may pose a challenge to federal research planners as other federal agencies have also expanded their research laboratory capacity, including BSL-3Ag space, providing alternative venues for performing such research.[55]

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[51] National Research Council, *Critical Needs for Research in Veterinary Science*, (National Academies Press: Washington, DC) 2005.

[52] House Committee on Science, *An Overview of the Federal R&D Budget for Fiscal Year 2007*, Committee Serial No. 109-35, February 15, 2006.

[53] Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification*. The NBAF was initially estimated at 500,000 square feet with ten percent being BSL-4 laboratory space. 71 *Fed. Reg*. 3107-3109 (January 19, 2006). Other scoping documents place the size of the NBAF at 520,000 square feet. See online at [http://www.dhs.gov/xlibrary/assets/nbaf-scopingmeetingmaterials.pdf].

[54] PIADC has a combined office/laboratory space of 226,560 square feet, excluding other buildings. USDA, "Report on the Strategic Planning Task Force on USDA Research Facilities: Report and Recommendations," August 1999.

[55] For example, USDA has invested in expanded BSL-3Ag laboratories at both the National Wildlife Research Center in Fort Collins, Colorado, and the National Centers for Epidemiology and Animal Health in Ames, Iowa.

Table 6. Estimated Use of NBAF Space by Gross Square Footage

Space	Gross Square Footage
Office/Administrative	35,000
BSL-2	30,000
BSL-3	372,000
BSL-4	55,000
Vaccine Production	12,000
Total	504,000

Source: Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification*.
Note: BSL-2 space includes laboratory and support areas. BSL-3 space includes laboratory, agriculture threat containment, and training and support areas.

The ability of DHS to effectively use the newly constructed BSL-4 and BSL-3Ag laboratories may depend on efficient interagency cooperation in order to identify other agency research activities that could benefit from being performed at NBAF. The DHS and USDA investment into research areas done currently at PIADC may also need to increase to fill the expanded capacity. Analytic study assessing the current and future needs for BSL-3Ag and BSL-4 research may aid DHS and USDA in effectively using the NBAF.

Coordination of Research Activities with Other Agencies

Since the NBAF would replace PIADC, research at NBAF is expected to be collaborative between USDA and DHS. At PIADC, DHS and USDA cooperatively set research priorities, based on risk assessment and other information. Generally, USDA performs basic research activities while DHS develops the results of that research and attempts to translate them into practical applications.[56] However, since NBAF also represents an expansion in capacity and capabilities over PIADC, this relationship may change. Establishment of the new facility provides an opportunity to evaluate previous agreements and make adjustments. Assignment of lab space to the Department of Health and Human Services or other agencies may require reevaluation and updates to these procedures.[57]

The USDA and DHS have testified that their current agreements have served them well at PIADC, with respect to both daily operation and transfer of technical

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[56] For further discussion of how USDA and DHS cooperate at PIADC, see Government Accountability Office, *Plum Island Animal Disease Center: DHS and USDA Are Successfully Coordinating Current Work, but Long-Term Plans Are Being Assessed*, GAO-06-132, December 2005.

[57] Because of the NBAF focus on foreign animal disease, agencies beyond USDA and DHS may have limited roles. Department of Homeland Security, personal communication, September 17, 2007.

information regarding research results and priorities.[58] Such interagency coordination may be essential in case of a crisis or in dealing with an outbreak of animal disease. The extent to which all agencies engaged in the NBAF agree on how to coordinate roles and responsibilities may prove to be a key factor in maintaining clear lines of authority and information and may be crucial to effective oversight of the facility.

The 110th Congress is considering these issues. Under H.R. 1717 (ordered to be reported by the House Homeland Security Committee on August 1, 2007), the NBAF would be run by a director appointed by DHS in consultation with USDA. The director's role would be limited to operating and maintaining the facility, including ensuring security and emergency response plans. This role is less broad than in a previous version of the bill, which would have also given the DHS-appointed director authority over all research programming at the facility, including USDA research. In the committee-amended bill, in addition to the director, separate directors of research would be appointed from DHS and USDA to oversee the research programs of each department. The USDA and DHS would develop a "joint strategy" defining the roles of USDA and DHS at the NBAF.[59]

Timeliness of Construction Activities

When complete, NBAF would eventually house all the research activities underway at PIADC. The DHS considers PIADC to be approaching the end of its design lifetime. Finishing construction of the NBAF and achieving operational status before down-sizing or decommissioning PIADC is dependent on timely construction activity. Because of the unique research currently performed at PIADC, the smooth transition of this capacity may be an issue of congressional concern. Beyond the transition of research projects, programs, and supplies, transfer of personnel and retention of an experienced workforce may also pose a challenge to DHS and USDA.

The original schedule for the NBAF, as presented to Congress, proposed finishing construction and commissioning the NBAF in FY2010. Since then, the

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[58] House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, "Reducing Threats to Our Nation's Agriculture: Authorizing a National Bio and Agro-Defense Facility," *Hearing Transcript*, May 23, 2007.

[59] In 2004, the USDA and DHS developed "A Joint DHS and USDA Strategy for Foreign Animal Disease Research and Diagnostic Programs" to coordinate their activities with respect to activities at PIADC. While this strategy has not been made public by DHS or USDA, it has been discussed in congressional testimony. See Testimony by Edward Knipling, Administrator, Agricultural Research Service, Department of Agriculture, before the House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, on May 23, 2007. The DHS has not updated this strategy. Department of Homeland Security, personal communication, September 17, 2007.

proposed schedule has been extended twice, first having operations begin in FY2013,[60] and most recently having operations begin in FY2013 to FY2014.[61]

The extension of the NBAF construction schedule increases the time that PIADC will be in operation. The PIADC has historically had security, coordination, and other issues.[62] The DHS has developed and implemented a multi-year *Corrective Action Plan* to address these issues and maintain the operation of PIADC.[63] Since PIADC has been identified as approaching the end of its design lifetime, extended operation and maintenance of these facilities may not be as cost effective or as efficient for the research endeavor as completing and transitioning research to the NBAF. The DHS spent approximately $24 million in FY2007 and $17 million in FY2008 to upgrade the facilities at PIADC, and requested approximately $17 million more for FY2008. The DHS did not request additional appropriation for upgrades in FY2009[64] and does not plan to in future years.[65] The upgrades include designing a new animal wing and continuing activities described in the *Corrective Action Plan*. The DHS expects completion of these upgrades in FY2010.[66] Further NBAF construction delays may require additional funds be used to support PIADC's corrective maintenance.

Future Use of PIADC

The DHS has yet to determine what actions to take with the PIADC when construction of the NBAF is completed. The DHS has stated that one of the main goals of the NBAF is to expand upon the existing PIADC research. According to DHS, once NBAF is operational, PIADC research activities will transfer to it.[67]

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[60] See online at [http://www.dhs.gov/xlibrary/assets/NBAF_Timeline.pdf].

[61] See online at [http://www.dhs.gov/xres/labs/gc_1170798884583.shtm].

[62] See General Accounting Office, *Combating Bioterrorism: Actions Needed to Improve Security at Plum Island Animal Disease Center*, GAO-03-847, September 2003; and Government Accountability Office, *Plum Island Animal Disease Center: DHS and USDA Are Successfully Coordinating Current Work, but Long-Term Plans Are Being Assessed*, GAO-06-132, December 2005.

[63] According to DHS, the total cost of the *Corrective Action Plan* is approximately $56 million. The *Corrective Action Plan* was reported to Congress by DHS in FY2005. Department of Homeland Security, Office of Inspector General, *Additional Physical, System, and Management Controls Can Enhance Security at Plum Island (Redacted)*, OIG-07-43, May 2007.

[64] Department of Homeland Security, Science and Technology Directorate, *Fiscal Year 2009 Congressional Justification*.

[65] Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2007-2011*, May 2007.

[66] Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2007-2011*, May 2007.

[67] Ibid.

The fate of the PIADC, once current research activities are transferred from it, remains unclear. The DHS has identified that "proper decontamination and decommissioning (D&D) of the facility after the transition will be critical to meet regulatory compliance and eventual disposal of the site."[68] The DHS has not stated when or how this process might occur. In discussing the development and construction of the NBAF, DHS has stated, with regards to PIADC, that "no decision has been made as to the future of Plum Island."[69]

The DHS is currently investing money to improve and upgrade the laboratory facilities. Continued use of PIADC either by DHS in some other capacity or under the control of some other entity remains an option. Alternatively, following decommissioning, the laboratories might be removed and the site used for a different purpose. Although many local officials have opposed expanding the number or type of pathogens researched at PIADC, some have expressed support for the continued operation and existence of the facility, because of its economic value to the surrounding area.[70]

Selling Plum Island. One option raised by DHS has been to sell Plum Island and use the profit from such a sale to offset the construction costs of the NBAF, the decontamination and remediation costs for the island, and the demolition costs for the PIADC. Under this proposal, DHS would sell Plum Island in FY2009 or FY2010, arrange with the purchaser to allow operations to continue until the NBAF construction was finished, and transfer Plum Island to the purchaser only after clean up of the island had been completed.[71]

Most sales of surplus property are handled by the General Services Administration and any funds received redirected into the Treasury.[72] The DHS has proposed to add statutory language to the FY2009 DHS appropriations act providing express authority to liquidate the Plum Island assets and retain the proceeds of the sale. The proposed language indicates that these funds could be used to offset costs associated with construction of the NBAF; however, the proposed language would also allow the DHS Secretary to use the net proceeds of the Plum Island sale for "other real property capital asset needs."[73] Under this proposed language, the net proceeds from the sale of Plum Island would be retained by DHS until fully spent rather than reverting to the Treasury at a future date.

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[68] Ibid.

[69] Bill Bleyer, "Homeland Security Seeks Input on Plum Island Disease Lab," *Newsday*, August 21, 2007.

[70] Ibid.

[71] Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification*.

[72] For a brief overview, see CRS Report RS20630, *Surplus Federal Property*, by Stephanie Smith.

[73] Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification*.

The amount of money that might result from liquidation of the Plum Island assets is uncertain. Fluctuations in remediation costs for environmental clean-up of the island and property values, for example, contribute sizeable uncertainty to any estimate of a future sale's proceeds. The sale might provide net funds insufficient for the construction of the NBAF or might provide substantial surplus funds even after the NBAF construction is complete.

Policymakers, in considering DHS's proposed language, may weigh the value of having offsetting revenue for current and future construction performed by DHS against the potential for lessened congressional oversight of DHS capital construction projects. By providing such authority, Congress may be lowering DHS's burden for justifying construction projects, as new appropriations might not need to be requested for each project. In contrast, having a secure, readily available source of funds might allow DHS great flexibility and efficiency in planning and executing future construction projects.